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TITLE OF THE INVENTION

SYSTEM AND METHOD FOR PROVIDING TEMPORAL PATIENT DOSING

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CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of copending PCT International Application number PCT/US00/35048 filed on December 22, 2000 which claims priority from U.S. provisional application serial number 60/176,961 filed on January 18, 2000, and serial number 60/172,057 filed on December 23, 1999.

STATEMENT OF FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

REFERENCE TO A MICROFICHE APPENDIX

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Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains generally to internet-based distribution of medications and supplements, and more particularly to a method for packetizing and distributing individualized custom doses containing a combination of medicines and/or supplements created according to a user defined dosing schedule.

2. Description of the Background Art

Individuals are taking an ever increasing variety and number of both supplements and medications. Each of these individuals has very unique requirements as to the type and concentration of pills being taken. However, pharmaceutical manufacturing and distribution systems are designed for mass distribution in large quantities and have not addressed these individualized needs. Currently, a consumer taking a combination of medications and/or supplements, herein referred to as MS, is required to purchase containers of the various supplements and medications. Typically, these are purchased in plastic and glass bottles. A few generic pill combinations are available in packets and other containers, however, such packets comprise merely a generic supplement, that were it not for size limitations could be placed in a single generic "multivitamin" pill. A large category of "multi" pills exist on the market and many are directed at specific segments of the market, such as aging men, aging women, and those under stress. One manufacturer of "multi" pills (as in multivitamin, multi-mineral, etc.), has begun to allow users to have some control of the ingredients within their multi-pill, should they order sufficient quantities. However, it will be appreciated that a generic pill, or a generic set of pills does not provide MS doses to the consumer which are tailored to his/her specific set of requirements, containing the proportions of herbs, vitamins, over the counter pharmaceuticals, and prescriptions which are suited to the given individual.

According to current practice, consumers gather a collection of various supplements (vitamins, minerals, herbs), medications (over the counter, prescription), which have been found to be the most beneficial. The number of MS being taken within the population continues to increase and even young healthy individuals may take

groups of between 10-20 pills two or even three times per day. It will be appreciated that once a collection of pills is obtained, the consumer becomes the pharmacist in charge of this miniature "pharmacy". In order to properly operate their miniature pharmacy, it would be far preferable if the consumer had a full understanding of the benefits and contraindications of each pill, the amount of each medication/supplement to be taken, and the possible interactions between the various medications/supplements that they have in their stock. In addition, to employ their miniature pharmacy, the consumer is required to open up each of the containers from one to four times per day in order to collect an MS dose for that particular time of day. The burden can be somewhat alleviated by the use of a pill container having compartments for storing collections of pills so that one can collect up to a weeks worth of doses at a time. However, such segmented containers remain inconvenient, and are difficult to take to work or when traveling, such as on business trips. Furthermore, the consumer is required to manage their inventory of medications and supplements (MS) and must order or purchase locally new containers of each MS as necessary. It will be recognized that each container of pills becomes depleted at times which are independent of the other MS, thereby leaving the consumer in the position of continuously purchasing replacements for one or more of the supplements or medications.

Additional problems exist with the current manner of dispensing these medications and supplements (MS). The consumer needs to keep track of times at which doses are to be taken, and remember to take each of the doses. Furthermore, the consumer is required to plan ahead to assure that their pills will be with them if they

are not at home, for instance if they are partaking of an evening dinner, or a party, they may easily miss a dose. Often, a consumer will forget either to take a dose, or forget that they have taken a dose, wherein they take an additional dose or miss a dose. Misdosing is very prevalent amongst senior citizens, especially the millions suffering from memory loss, or Alzheimer's disease. The prevalence of miss-dosing is well documented and a recent study has found that within the United States that more individuals die each year from dosing errors, than die in automobile accidents. A number of mechanical devices are available which attempt to meter out pills or record when pills are taken by a consumer; however, these do not alleviate the underlying problems, such as the need to maintain a stockpile of MS, or the inconvenience.

Requiring individuals to collect and dispense from their own pharmacies is subject to significant degree of risk. Medications are forgotten, taken incorrectly, mixed improperly, and so forth. The overhead of keeping a miniature pharmacy stocked up and remembering what, how, and when to take it all is burdensome to anyone, but is especially onerous to our senior citizens which must deal with the most complex assortment of medications and supplements. A study of seniors in nursing facilities found that on average each individual took over seven medications, or supplements a day, and the number is on the rise. Due to the difficulties with orchestrating each pill dose, it is not surprising how often people forget, or make dosing mistakes with even their most important medications.

Institutional care organizations, such as hospitals, nursing homes, and the like, suffer from another set of problems associated with providing doses of supplements and medications to their patients. Institutions have a staff which maintains the various

supplements and medications; often distributing them to the patients. The overhead and liability associated with creating and supervising these numerous doses each day for every patient becomes exceedingly costly and prone to error. It will certainly be appreciated that the inventory of supplements and medications at an institution must be carefully managed, assuring adequate supplies, proper storage conditions, proper dispensing conditions, preventing theft, and assuring that expiration dates are taken into account. Care staffs need to remain vigilant to be certain that each patient gets the proper doses, and that doses created for one patient are not received by another patient. Misdosing of patients within an institutional setting can have dire consequences, and numerous patients die each year as a result. Furthermore, additional problems exist with regard to theft and loss of both medications and supplements. In addition, staffs do not have the time to study each of the medications to determine if any possible interactions or contraindications may exist.

As can be seen, therefore, the development of an improved dispensing method for both consumers and institutions that would eliminate the necessity of managing a miniature pharmacy while increasing safety and convenience. The system and method for providing temporal doses in accordance with the present invention satisfies that need, as well as others, and overcomes deficiencies in previously known techniques.

BRIEF SUMMARY OF THE INVENTION

The present invention is a system and a method for providing persons with individualized (custom) doses of their recurrent supplements and medications. The word "Dose" was derived from the Greek word "dosis" which means "gift", while the word "temporal" refers to time. The right dose at the right time is a gift to the health of

each individual. The present system and methods may hereafter be referred to as "individualized dosing system", or simply as "system".

The system comprises an interface, such as a web site on the World Wide Web (Internet), for allowing a consumer, or institution, to generate an order for individualized doses of supplements and/or medications which may be fulfilled by a packetizing system. By way of example and not of limitation, the consumer establishes a dosing schedule into which is entered a custom array of medications and/or supplements (MS) from a database associated with a pill repository. An order may then be placed for a series of these customized temporal doses, wherein each temporal dose, which may contain an assortment of MS, is separately packetized and the series of temporal doses shipped to the consumer. The consumer enters the dose information via an interface which is associated with, and communicates with, a computer system which can direct a packetizing system for the packaging of the pills, or other forms of supplements and/or medications, for use by the consumer. The interface of the computer system is configured to require authorizations from a physician, or other authorized medical practitioner, when any prescription medications are selected. Furthermore the interface is configured to execute a purchase transaction for the selected MS within the order at the discretion of the consumer.

Preferably, the packets are marked, or labeled, with a textual and/or graphic indicia which preferably contains the patient's name and the scheduled date and time at which the MS dose is to be utilized. The consumer, or institution, is thereby no longer burdened by the maintenance of a miniature pharmacy while numerous concomitant safety and convenience features are provided. The term medications and supplements

(MS), as used herein, comprises any variety of medical and/or health related solid, or semisolid pill, for instance, conventional pills, capsules, caplets, gel caps, and lozenges. The abbreviation "MS" used herein is inclusive of new pill packaging forms as well, since solid pill forms constantly evolve and their use within the system would be obvious. Although the present system follows the largest segment of the MS market, which is solid form MS, embodiments are additionally described for the delivery of liquid forms of MS within the system.

By way of example and not of limitation, an individual consumer can interface to an individualized dosing system which collects consumer dose information and prepares MS dose packets by way of a web site interface. The consumer typically would register by establishing their identity and configuring a number of use parameters. The consumer then establishes a dosing schedule on the system and populates it with MS selected from a database; the database may include MS selected from a master MS library, MS template, MS library from a recommended source, or a personal library selected as a subset of the master MS library. The system generally being defaulting to represent MS that is currently in stock (or to be in stock by the required time) at a temporal dose fulfillment center. Furthermore the invention preferably allows the consumer to elect to view a master MS library containing a superset of the MS that is currently available. A consumer interested in a particular MS found in the master MS but not in-stock for fulfillment may enter a request or post a suggestion from the system.

A variety of forms of dosing profiles are supported, so that dosing may follow according to a pattern which provides optimum results. It is often desirable to follow a

profile, such as accelerated dosing, decelerating dosing, or interrupted periodic dosing, it has traditionally been sufficiently difficult to achieve simple compliance, wherein the confusion of traditional profile dosing can reduce compliance and negatively impact results. The system provides seamless profile dosing, in which the consumer enters the pattern (or is it entered by practitioner or from a manufacturer site) and the dose changes are automatically implemented. For example, it is typically recommended that the herb Echinacea, which is taken to increase an individuals resistance to viral infection, not be taken on a continuous basis. It is strongly recommended that Echinacea be taken following interrupted periodic dosing, wherein the herb is taken for a week or two, halted for a week or two, taken for a week or two, and so forth.

Medications are often more effective when taken in quantities that either increase in strength or decrease over a period of time. Furthermore, it is prudent when adding a new medication or supplement to introduce a lower initial dose level until it has been determined that new MS will not adversely affect the consumer/patient.

The system increases consumer safety by preferably performing assessments of the selected MS for possible interactions with one another. In addition, if an optional medical profile is entered, such as by the consumer, by a medical practitioner, or by collection or linking with a personal medical database, which contains information relating to their health and conditions, the system assesses the selected MS against the consumers medical profile for possible clinical contraindications for use. The consumer/patient is alerted to possible side effects, and in some cases is urged, or even forced, to alter their selections to suit prudent medical practice. Once the individualized dosing schedule has been established and populated, the consumer may

submit the order for various forms of pre-order verification; such as to their doctor, pharmacist (or other party); their insurance company to determine payments therefrom; or they may submit the order directly for fulfillment.

The system contains a large medication database operably connected with an ERP system, or similar, such as of a pharmaceutical distributor, that in combination directs a specialized fulfillment system with a packetizing system that is capable of creating arrays of individualized custom patient doses for shipment to an individual, or institution. The packetizing system fulfills orders for each consumer, or institution, with a conveyance system which interconnects a series of pill dispensing bins, or equivalent, which collectively define a pill repository. The conveyance system includes dose bins, or compartments, for collecting an assortment of MS into an individual dose. The conveyance system is moved in concert with the control of dispensing pills from the pill dispensing bins so that the requested doses are properly collected within the bins or compartment of the conveyance system. The conveyance system may be considered as a "dose collection array" (DCA) associated with the doses of the order which are to be filled with assorted MS from the pill repository. The DCA traverses a series of MS dispenser bins which are configured for controlled selective dispensing of MS.

Preferably, the MS dispensing bins are implemented to verify that proper MS are correctly being collected. Once all MS is collected in association with the individualized doses of the order, the DCA is received within a packetizing station which preferably verifies the MS of the individualized doses once again prior to packaging and labeling each of the doses within the order. The orders are then packaged and shipped to the consumers, or institutions, which receive an ordered set of individualized custom doses

which are labeled according to the dose schedule which has been established. By way of example, a vehicle driven by linear electromagnetics is retained within a tubular track for collecting the pills associated with each dose as it travels along a track that traverses a series of pill dispensing bins.

5 The temporal dosing system of the present invention saves ordering and other consumer-related information for subsequent use, wherein the consumer can elect to place a recurrent order in which the selected doses are generated in a subsequent order without the need to place a new order. For example, the consumer may elect to order their supplements monthly, but want them sent automatically by a given date. Changes to the dosing schedule are then incorporated within the subsequent order or sent as separate pills, or as a "piggyback" set of doses. A consumer, or other party authorized on behalf of the consumer, is required to be sufficiently identified prior to logging in as a specific consumer and thereby gaining access to said consumer information.

15 An object of the invention is to create individualized custom doses of medications and supplements (MS).

 Another object of the invention is to provide convenient ordering of MS doses in periodic quantities, such as monthly.

20 Another object of the invention is to provide MS doses in synchronized quantities whereby an individual consumer need not check and maintain stocks of various MS which are being depleted at different rates and times.

 Another object of the invention is to increase the level of compliance for the taking of prescription medications.

Another object of the invention is to provide MS as dose packets that are labeled for the date and time they are to be taken.

Another object of the invention is to provide a convenient mechanism by which one or more individual doses may be carried easily when the individual will not be at home at the time the dose is to be taken.

Another object of the invention is to provide an MS dissemination mechanism wherein a patient need not remember what and how many of each supplement or medication is to be taken at each varied dose interval.

Another object of the invention is to provide pre-collected doses of supplements and medications such that the individual need not open containers and individually collect MS for each particular dose.

Another object of the invention is to provide a dose dissemination method that supports accelerated and other forms of scaled dosing while not relying on the patient to administer this more complex dispensing profile.

Another object of the invention is to provide an ordering mechanism in which checks are made for interactions and dose levels between the various supplements and medications within a patient dose so as to increase safety and promote health.

Another object of the invention is to provide a dose dissemination mechanism wherein doctors can order prescription medicines as doses integrated with the doses already being taken by the individual.

Another object of the invention is to provide a dose dissemination mechanism wherein doctors can check the supplements and over the counter medications being taken by the patient to assess possible interaction risk and contra-indications.

Another object of the invention is to provide a mechanism for the distribution of supplements and medications that may be used within hospitals to reduce overhead and dosage errors associated with collecting individual doses.

5 Another object of the invention is to improve cleanliness in relation to the dispensed medication.

Another object of the invention is to reduce the number of dosing errors and thereby increase both safety and health factors in taking supplements and medications.

Another object of the invention is to provide an automated system for fulfilling individualized custom dose orders with limited human interaction.

10 Another object of the invention is to provide a system capable of being easily scaled to any size repository of MS, so that a wide variety of custom doses can be created.

15 Another object of the invention is to provide a system wherein supplies of the various supplements and medications are stored for dose retrieval in a high-density configuration to maximize space utilization.

Another object of the invention is to provide a high-speed system for fulfilling temporal dosing orders.

Another object of the invention is to provide a system for packaging individualized doses that is highly reliable and easy to maintain.

20 Another object of the invention is to provide a system in which particular medications and supplements may be replenished while the dose temporal dosing system is still operating.

Another object of the invention is to provide a system in which multiple levels of dose checking can be provided to assure that the correct dose has been collected.

Further objects and advantages of the invention will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

FIG. 1 is flow diagram for temporal patient dosing according to the present invention, wherein individualized custom doses are scheduled and ordered over the Internet, packaged into a set of individualized doses and delivered to the consumer.

FIG. 2 is a plan view of individualized custom doses packaged according to an aspect of the present invention, and shown with patient name and dose time.

FIG. 3 is a perspective view of a package for dispensing a set of individualized custom doses as shown in FIG. 2, according to an aspect of the present invention.

FIG. 4A is a side view of sealed cup form of packaging according to an aspect of the present invention, shown exemplifying use with solid pills.

FIG. 4B is a side view of sealed cup form of packaging according to an aspect of the present invention, shown exemplifying use with a liquid dose.

FIG. 5 is a flowchart of an individualized dosing method according to an embodiment of the present invention shown exemplifying a consumer creating individualized custom doses according to a dosing schedule.

FIG. 6 is a flowchart of an enhanced individualized dosing method according to an embodiment of the present invention.

FIG. 7 is a flowchart of individualized dosing for use with institutions according to an aspect of the present invention, and showing the process of ordering the sets of individualized doses.

FIG. 8 is a flowchart of individualized dosing as per FIG. 7, showing the order fulfillment process.

FIG. 9 is a page diagram of the info pages on a web site according to one embodiment of the present invention showing the relationship between the web pages.

FIG. 10 is a page diagram of the individualized dose selection pages as continued from FIG. 9.

FIG. 11 is a screen exemplifying a browser shown in the process of selecting MS for inclusion in a personal library as selected from a master library, as provided according to an aspect of the present invention.

FIG. 12 is a screen exemplifying a browser shown in the process of defining and populating a dose schedule according to an aspect of the present invention, showing numerous MS already established within the schedule.

FIG. 13 is a plan view of an individualized custom packetizer according to an aspect of the present invention, shown with four pill towers and a packetizing station interconnected by a set of fixed traversal paths.

FIG. 14 is an elevation view of an MS bin according to an aspect of the present invention.

FIG. 15 is a side view of the MS bin of FIG. 14.

FIG. 16 is a hierarchical diagram of computer resources utilized according to an embodiment of the present invention.

FIG. 17 is a flowchart for a manufacturing process for creating the individualized
5 custom doses according to an embodiment of the present invention.

FIG. 18 is a top view of a compartmentalized dose assembly vehicle (*comdav*) according to the present invention.

FIG. 19 is a side view of the *comdav* depicted in FIG. 18.

FIG. 20 is a cross-section view of the *comdav* of FIG. 19 shown with an MS
10 collection path.

FIG. 21 is a cross-section of a linear-driven tubular path exemplified for use by the *comdavs* according to an aspect of the present invention.

FIG. 22 is a side view of a strip of inductors exemplified for use within the linear electromagnetic drive according to an aspect of the present invention.

FIG. 23 is a top view of individualized doses according to the present invention
15 shown packaged within glassine packets.

FIG. 24 is a top view of piggyback dose packaging according to an aspect of the present invention.

FIG. 25 is an elevation view of an MS tower according to an aspect of the
20 present invention shown partially loaded with a single *comdav* traversing a linear drive tube.

FIG. 26 is a cross-section view of the MS tower of FIG. 25 showing the twin rows of bins and bin access provided from above.

FIG. 27 is a end view of a tubular vehicle path through which a *comdav* is to travel according to another embodiment of the present invention.

FIG. 28 is an end view of a *comdav* configured for operation within the tubular vehicle path of FIG. 27.

5 DETAILED DESCRIPTION OF EMBODIMENT(S)

Referring more specifically to the drawings, for illustrative purposes the present invention is embodied in the apparatus generally shown in FIG. 1 through FIG. 28. The detailed description exemplifies specific embodiments of the invention which are described in sufficient detail so as to allow a person of ordinary skill in the art to practice the invention without undue experimentation. It will be appreciated that the apparatus may vary as to configuration and as to details of the parts without departing from the basic concepts as disclosed herein.

An overview of the general process for providing temporal patient dosing 10 according to the invention is given by FIG. 1. An individual 12, also alternately referred to as consumer, patient, or user, is operating an internet enabled computer or appliance 15 14, accessing through the Internet 16 a web site hosted by a web server 18. Within the web site the individual can establish a dosing schedule by selecting the times during each day and the medications and/or supplements (MS) to be taken at those times. The web site served by the web server 18 sends orders and operates with data 20 provided by an MS data base server 20. It will be appreciated that alternative forms of data communication, such as electronic data interchange, XML, and so forth may be utilized to allow the consumer to establish dosing schedules and select the elements within the doses. Furthermore, the communication system may be integrated within, or

operate in conjunction with an institutional computer system, such as a hospital, nursing-home, and similar systems that may act as a consumer on behalf of a patient. It should also be appreciated that institutions often prefer their own interface wherein alternative communication protocols are established for communicating the dose

5 information to the temporal dosing system without departing from the present invention. Preferably, however, the fulfillment portion of the invention operates with a web site interface. Orders are routed through a portion of a backend server, here exemplified as a set of ERP software 22 (Enterprise Resource Planning) for tying in the various ordering, stocking, and other services for the MS doses order. The ERP software 22

10 also qualifies orders and determines if another of the distribution sites should handle the order. Additional corporate systems 24 may be tied in for managing associated corporate activities. A factory automation system 26, which is associated with the temporal dosing system, receives the processed orders which have been checked by the ERP system 22. The factory automation (FA) system 26 interfaces with equipment

15 within an MS repository and packetizer system 28. A set of packets 30 for the consumer 12, is shown comprising a series of packets 32a through 32z. It will be appreciated that although it is preferable to separately retain each of the doses within individual packets which are joined to one another in a given order such as date sequential for a single patient, or by patient number (for multiple patients within an

20 institutional setting); the doses may be alternatively packages in any convenient form which allows a set of MS which was selected to be taken at a given time to be easily retrieved for use by the consumer without departing from the present invention. Each individual packet is preferably configured with an indicia containing information about

whom the individualized dose has been created for, and the time that the dose is to be taken. For example each packet may contain the name of who is to take the packet, for example "John Q. Doe" and their address, should the packet get misplaced, "1564 Motherlode Drive, Gold River, CA. 95670". Each Dose packet preferably contains the date and time the dose is to be taken, for example a series may appear as: "8:00 AM on Tuesday, Feb. 1, 2000", "2:00 PM on Tuesday, Feb. 1, 2000", "8:00 PM on Tuesday, Feb. 1, 2000", "8:00 AM on Wednesday, Feb. 2, 2000",..."8:00 PM on Tuesday, Feb. 29, 2000". The packet may include additional information such as "Take with food" and any other precautions. Inserted instructions or content list may also be included within each packet. In addition, the packet may contain information listing information about the supplements contained therein. The string of individualized packets is boxed with any other portions of the order 34, and shipped, as represented by truck 36. The order 34 arrives at consumer 12 containing a series of individualized doses configured by the consumer according to a dosing schedule and packaged for convenient use.

Further shown in FIG. 1 are a medical link 38 and a prescription link 40. The medical link provides numerous functions which allow a medical practitioner, or other health professional, to be involved with the individualized dose ordering process. For example, the doctor may verify an order of an individual prior to the order being fulfilled. The doctor may also, if so directed by the patient, directly edit the schedule and MS selection of an individual pending approval by the patient. The doctor may also directly enter prescriptions into the system for a particular patient, subject of course to patient approval. The prescription link 40 may be utilized similar to the medical link 38, however it provides an interface for pharmacies. Organizations with a fiduciary

relationship with the consumer, such as an insurance carrier, may also gain access to the system with the prescription link 40, or similar, at the consent of the patient to allow for insurance company authorizations, payments, or advise regarding coverage of the selected MS doses. To facilitate recommendations and dosing supervision, the system provides for a time and/or access sensitive password to be issued by any registered user. The patient can thereby give a temporary password to a health practitioner so that the practitioner may review the dosing schedule which has been established and make suggestions. Notes can be left with the advise so that the recommendations can be more readily understood.

FIG. 2 depicts a set 30 of individualized custom doses 30 exemplified as being contained within sealed glassine packets. At least a portion of three separate individualized doses 32b, 32c, 32d, are illustrated in FIG. 2 with a container portion of the packet 42 retaining MS 44 selected according to a schedule established by the consumer, or health-care institutional proxy thereof. Information about the packet, such as who is to take the individualized dose and when is it to be taken are preferably provided within an indicia 46 that is either directly applied to the packets, or on labels. An optional bar code, or other machine-readable mechanism, may be incorporated within the package to allow for registration within an institutional setting. The packets 32b – 32d are shown in a tear-away configuration having a perforated seam 48 between each packet.

FIG. 3 illustrates the string of packets containing individualized custom doses, such as 32c, loaded within a packet reel 34 that is capable of functioning as a shipping container as well. The packets preferably exit the packet reel 34 at a slot 50, and the

packet reel 34 is preferably configured with consumer information 52 to assure receipt and use by the proper individual, in addition to machine readable indicia such as a bar code 54. The indented circular area 56 provides for retaining a cylindrical packet retention core (not shown) in the proper position within the packet reel 34.

5 FIG. 4A depicts sealed dose cups 60 according to another aspect of the invention. The dose cups 60 have a cup portion 62, a lid 64, and preferably a pull-tab 66 to facilitate removal of lid 64. The dose cup 60 is shown retaining solid form 44 MS. FIG. 4B illustrates a dose cup being used for retaining a quantity of liquid form 68 MS.

10 FIG. 5 shows a general flowchart 70 of a consumer ordering a set of individualized doses over a web site. The process starts 72 as an individual logs on 74 to the site. New users detected at block 76 are directed into an account initialization routine 78 within which the identification of the consumer is established and the parameters of use are determined and/or disclosed. A dose schedule 80 is set up by the consumer to establish the times during each day (a 24 hour period) that a dose is to
15 be taken. A day may be broken down into any number of dose intervals, for instance individuals commonly take supplements from one to three times daily, while medications are typically scheduled within doses to be taken from one to four times daily. The consumer determines the times at which each collection of MS comprising a dose is to be taken, unless over-ridden or countermanded by the supervision of an authorized
20 health-care practitioner. Usually, the consumer elects the default case wherein all doses for the month follow the same set of dose intervals, however, the user is alternatively allowed to set different time periods for each day, and different schedules for each week within a given month, or other selected time period over which the doses

are being collected. It should be recognized, however, that the time periods selected are those attached to the specific dose packets, and that the individual may alternately elect to name the doses, such as "morning" and "evening", or "morning", "noon", and "night". The selection of a dosing schedule allows the consumer to set the name of the time period that they are comfortable with. Within an institutional setting, the time periods are selected by medical practitioners in accord with established facility protocols. Custom dose profile intervals may be programmed that allow the user to fit a varying dose schedule into a week or month. Custom dose profiles also allow the user to add specific supplements to a weekly or monthly regimen based on activity, for example wherein an overlay of doses is added, or subtracted, from a base-line set of standard doses. One application of this would be the case in which anticipated high aerobic activity during a weekend may require different supplements than high stress activity during the workweek. Custom dosing can be entered at any time, and preferably allows for customization within each given week or over longer periods such as the month, or extended to multiple months. If a weekly view of the dosing schedule is selected, then a seven day week is shown and the user can add or subtract MS from any of the days of the week. Each week within the month will then be generated with this custom week dose profile. Upon switching to a month view of the dosing schedule, then the user can perform the same over that period of a month. A month span is often useful especially for those that user regular fasting or other monthly activities. An athlete may perhaps log on and set a new order each month based upon their training and race schedule for the following month. Although the weekly and monthly views should provided sufficient selectivity for the majority of situations, the dosing schedule

may be viewed over any desired period of time. Typical consumers would generally establish between two to four dose intervals for each day of the week, although any number may be supported.

Specific MS are then selected at block 82, such as by MS category,
5 indication/desired, or by specific selection, for entry into the dosing schedule. The selected MS is then checked in relation to the other selected MS and information about the individual, at block 84, wherein the possibility of interactions is assayed and communicated to the individual. In some cases the system preferably will require that the individual select alter one or more MS comprising the dose if a significant risk is indicated, and will make suggestions as to alternatives. As an example of alternatives,
10 consider a consumer that has selected Glucosamine as one of the MS within the dosing schedule and they have a medical condition, or are taking a medication for which the taking of Glucosamine is contraindicated. The system selects other alternatives, such as Sam-E, and suggests these to the consumer. Once checked, the selected MS is
15 entered into the dose schedule at block 86. The individual continues entering doses, represented as the loopback at block 88, until all desired MS have been entered into the dose schedule. It will also be appreciated that for convenience the consumer may select to automatically add a particular MS to a particular day's dose spanning a week a month. The consumer can also elect to remove an MS that been entered into the
20 schedule on a week, month, or daily dose basis. The check for drug interactions and contraindications continues as the consumer populates the dosing schedule.

The completed schedule of individualized doses is then submitted at block 90. At block 92 the individualized dose order is checked to assure that billing, shipping and all

FIG. 6 depicts another embodiment 110 for providing individualized custom doses to a consumer, which utilizes a few enhancements in relation to FIG. 5. The individual enters the site at block 112 and logs onto the system at block 114. If it is a new user as determined at block 116, then a new account is initialized and a series of information is collected commencing with sufficient identification and billing information at block 120. As per block 122, the individual may continue on to specify the desired interface style to be used, the preferences and links for linking prescriptions into the system, the preferences and links for providing dose supervision, the preferences and links for getting information regarding insurance coverage in certain MS and for submitting claims for reimbursement, preferences can be entered to determine how the system will process and represent the order, including parameters facilitating the automatic fulfillment of individualized dose orders, wherein an automatic reorder is performed by a certain critical date if information, or new dosing information, is not otherwise received within the system. If selected by the user, the system is capable of placing recurrent orders without the need of user intervention, and will notify the user should a question arise as to the availability of one or more MS selected by the user for an upcoming order. Still further at block 124, the individual can enter the dosing interval, set the time span of the order along with start and stop times, select repetitive dosing parameters, and various user preferences. These setting may also be accessed via block 126, by any valid user entering the system.

The consumer establishes a personal library, a "short-list", to use for selecting MS at block 128, and may additionally tag selected MS entries to simplify later searches. It will be appreciated that the repository of MS associated with the system

may contain many tens of thousands of medications and supplements from which to choose. Therefore, the consumer (or medical professional within an institution) is encouraged to select a short-list within the library to speed the selection of MS for populating the dosing schedule. The selection of MS from the library into this "short-list" compiled by the consumer has a number of advantages. Once the consumer has compiled this short-list they need not peruse the huge MS database whenever changes to a dosing schedule are made. For example, from month-to-month a consumer may change the brand, or dosage, of a particular supplement, such as Grape Seed Extract. Preferably, they will have selected a few alternatives when compiling their short-list that they can select from each month, or other period, when setting up a new dosing schedule. A personal MS library short-list simplifies the entry of MS into the dosing schedule because the user need not vacillate between a selecting types of MS from a huge list, and the entry of these into a schedule by which they are to be taken. The short list also essentially provides a "scratchpad" area, or "personal apothecary", from which they may wish to choose at a future time. The system allows the consumer to enter notes into each MS that is pulled into their personal library short list. The personal MS library, short list, is provided to allow a consumer, (or institutional buyer) to select MS from the master library that they may wish to use now or in the future. Tagging of MS entries, allows the user to prioritize how lists are generated in relation to the master library. For example, entering a "selection priority" allows the individual to establish a relationship amongst a set of alternative choices that overrides preferences selected by the user. The individual may set their initial preferences for example to give priority to high-quality supplements, or alternatively; all natural herbals, or the lowest price

alternative. The individual may over-ride the base level preference with specific hierarchy within a particular class of MS. Other forms of tags preferably include "external", "suggested", "not suggested", and "PersList". External doses are those being taken external to this system, for example one is eating bulk Gingko Biloba. External
5 allows the person to track even their uses which occur outside of the system, which include bottled medications which for one reason or another are not being supplied by means of the system. "Suggested" doses are those which would normally be suggested by a health care practitioner. "Not Suggested" doses are those which are not recommended by the practitioner for the particular individual. MS marked with
10 "PersList" are retained in the short list of items pre-selected by the individual to simplify recurrent dose changes. The preceding tags were described by way of example and numerous other tags and variations can be created without departing from the teachings of the invention. It will be also be appreciated that the majority of users make few changes to the list of MS being taken, therefore, once the initial scheduling of
15 individualized doses are in place, the individual need not reenter MS or scheduling information unless and until a change is desired or necessitated. An MS manufacturer itself may be added to the "Not Suggested" category of the short list, in various situations, such as if the consumer does not like the quality or lack of environmental concern being typified by the manufacturer. In a similar manner, individual
20 manufacturers may be given a preferential rating wherein the display of the MS library (entire or personal) can be ranked according to consumer preference. It should be appreciated, however, that the consumer may bypass the use of personal MS library and alternatively select MS directly from the entire MS library database for insertion into

the MS dosing schedule.

In addition to a personal MS library, the system can support the use of any number of other subdivisions of the MS library. For example, health related professionals, organizations, magazines, and so forth may provide a ranking of the efficiency of supplements for the system wherein the consumer may elect to pull selections from one or more of these sublibraries. These sublibrary rankings from may take the form of templates provided by manufacturers, and recommendations from a variety of sources, from which a baseline personal MS library is established from which changes may be made. For example, the user may wish to utilize MS that have been well tested, and perhaps they download a list of from a consumer advocacy group of MS that have passed their testing. The user could then modify this list as desired, to suit specific purposes. Templates provide a pre-selected set of MS generally based on health parameters of the individual, such as for an individual that is hypoglycemic.

After establishing their own personal library from which to select MS, the individual may enter the MS at block 132 into the schedule they have defined. The important elements regarding prescriptions that are received within the system (preferably securely) may not be changed by the individual, although they may shift specified dosing intervals as long as the changes are minor and not of consequence to treatment. In addition, depending on the preferences which are established, the prescription may be filled with an alternative, such as a generic, as would be in keeping with various health-maintenance organizations. The MS being selected is evaluated in relation to the MS already loaded into the schedule to determine if any interactions, or other complications appear likely. The user is notified of these cases. A series of MS

may be entered into the schedule until all desired MS is contained within the schedule, as detected by block 134. Once the order of individualized custom doses has been defined by the user, they are provided with the option of having their dose schedule verified, at block 138. This may be performed in a number of ways to allow the individual to get feedback from their doctor, or other healthcare practitioner, or to alternatively determine insurance issues. The order is submitted, without verification if desired, and the manufacturing portion of the system then packages the individualized doses according to the schedule set by the user and ships the set of doses to the consumer at block 140, whereupon the session is terminated at block 142.

FIG. 7 illustrates processing of individualized custom doses 150 for individuals within an institutional setting. It will be appreciated that patient conditions within a institution, such as a hospital, can change rapidly and may warrant frequent delivery, such as daily, in contrast to the anticipated monthly or bi-monthly ordering by which individual consumers would tend to order their MS. The system therefore preferably handles the ordering the processing in a slightly different manner.

The system provides significant benefits for use by institutions such as hospitals, mental patient facilities, and nursing homes, to alleviate the burdensome overhead of dose procurement and dispensing. It should also be appreciated that the present invention is capable of reducing the number of dosing errors which cause more patient deaths each year than the number of people dying from automotive accidents. The institutions thereby can safeguard patient from dosing errors and reduce their liability from these mistakes by virtue of having the present system assemble each dose. The system can also collect the separate pills within a particular dose more safely at a lower

cost per dose than is possible within the hospital. However, since each hospital generally has its own systems and routines for performing daily operations, a custom interface and process of handling transactions with each hospital must be established to the system for providing temporal patient dosing. It is anticipated that in many cases an institution will use XML, or similar communication mechanisms, to integrate their own system with the present system exemplified by the web site functionality. Preferably the institution will integrate their system with the present invention, whereby the medical practitioners in charge of a particular patient can display a dosing chart for the patient, to which necessary changes may be made. These authorized changes are then communicated, such as by XML, over an IP connection to the dosing temporal dosing system of the present invention wherein the customized dosing may be provided. Preferably, the dosing orders would be communicated as a batch according to a schedule set by the institution, which allows for increased efficiency and additional checks on the MS being selected.

A method of processing an institutional order is exemplified. The authorized medical practitioner, or authorized institutional buyer, accesses the system at block 152 and logs on at block 154. The patient whose dosing is to be entered or changed is entered in block 156. If the patient is new, as detected at block 158, additional information is entered at block 160 which is exemplified by identification information, patient location (or delivery order) information, and the medical condition of the patient. The user is provided a wide assortment of choices regarding the scheduling of individualized doses, only a sample of which are shown in FIG. 7. Should the user elect to delete certain MS, as found in block 162, the change is performed in block 164. If the

user selects to add an MS, as per block 166, then the specific MS is selected at block 168 and an interaction check performed at block 170. If the MS does not fit within the established schedule, as determined at block 172, then the schedule may be revised so as to allow accommodation at block 174, and block 164. If an MS is not being added to the schedule, yet operations for this patient are not complete, as determined by block 176, then additional functions are accessed 178, to continue processing functions.

Once all MS for the patient have been entered within the system, then a notification/verification is posted to the user at block 180, and if all patient data has been entered, as per block 182, the user logs out 152. It should be appreciated that preferably the institutional systems will perform portions of the above functions, wherein the institutional purchaser is in the position of only needing to check elements of the order and facilitate any specific delivery needs.

FIG. 8 exemplifies a fulfillment process 190 within an institutional setting wherein individualized doses are delivered according to the present invention. The fulfillment process is triggered at block 192, typically by a time, or system status conditions wherein the fulfillment process is initialized at block 194 to an institution associated with the event condition. The patient record is incremented (i.e. from a "- 1" initial state) at block 196. If the last patient is detected at block 198, then the fulfillment list has been created, otherwise block 200 executes to check the listed MS doses for the patient and compare it with recently received information regarding, patient status, contraindications, and availability. If no problems are detected, then the data for the MS doses associated with this patient (generally a single day of doses) is added to the fulfillment list at block 202. After checking all patients associated with the institution, the

fulfillment list is sorted at block 204 into delivery order according to a delivery routing determined by the institution. The overall order parameters are checked and the list is transmitted at block 206 for fulfillment by the packetizing system. If orders for more institutions need to be processed as detected by block 208, then the institution is incremented 210 and the loop restarts; otherwise the session terminates until a new trigger condition is received. Packaging the individual doses is shown in a simplified three block process starting at block 214 wherein the individual doses according to the fulfillment list are collected and packaged, followed by shipment at block 216 and notification of shipment at block 218.

A number of common features are anticipated to be characteristic of institutional dosing. Daily deliveries of patient doses are expected to be standard practice for institutions such as hospitals due to the rapidly changing nature of patient dose schedules. The overhead and risk of daily deliveries is thereby mitigated by employing regional fulfillment locations for creating the doses, so that the package of doses will always be timely. Hospitals and their purchasing agents are expected to have additional needs for tracking and for speeding the process of loading dose schedules. In an institutional web site interface the dose administrator may set up general profiles used by each doctor for numerous conditions, these profiles can be modified and applied to a patient. Close monitoring of the dose selections are necessary with the number and frequency of changes required, and daily review and updating of patient doses may be necessary. Doctors may for example log onto a site and check the dose schedules for any of their patients.

Prescriptions can be entered by a doctors office, through a secured link (encoded) to a web site interface to the system. It will be appreciated that MS being taken short term (1-2 weeks) may be taken as a separate medication that augments the individualized custom dose packet. However, the system can accommodate even short term changes to a dosing schedule. The medication can be sent out as piggyback doses for the current month of doses, while a permanent or semi-permanent medication becomes part of the patients daily doses, as sent out monthly, for the time period as specified by the doctor. Alternately, if near the end of a month, then the pills can be added to the next months supply which could be sent a little bit early (reduces postage cost & increases convenience). Properly established, the burden of insurance billing can also be ameliorated. Generally the medicine, so prescribed, would be sent out later that same day or overnight. Regional distribution facilities with packetizing order fulfillment provide flexibility with regard to delivery of the dose packets.

Insurance companies tied into the system can be billed for doses prescribed over the network. A standard billing interface with the doctors offices is provided such that they need not deal with the vagaries of the individual insurance providers, while the system provides data in a format most suitable to each of the various insurance companies. These insurance companies can, at patients consent, review the established dose schedules. This data also provides useful statistical information for an insurance company.

FIG. 9 and FIG. 10 shows relationships 310 between a series of example web pages on which an embodiment for a temporal patient dosing web site is supports. A home page at block 312 is encountered upon first entry from which the user is provided

with a number of choices, including a collection of informational pages at block 314 – 326 which provide useful information on the company such as general company info, history, policies, consumer relations, investor relations, employment, and contact information. A site tour at block 332 is available, and the person browsing the web site

5 can access reports on various medications at block 328 and supplements at block 330. A registration entry at block 334 is provided for signing up individual consumers and placing orders on the system. After agreeing to the use policies of the system, the user may enter authorization information at block 336 to establish the parameters of their account. Additionally, the user is encouraged to enter insurance information at block 338 and personal/medical information at block 340. The entry of personal/medical information at block 340 is optional and confidential, however, it allows the system to provide enhanced interaction checking. For example, an individual may enter their age, weight, sex, specific medical problems, health goals, risk factors (i.e. smoker, drinker, hypoglycemic) wherein the data base can factor this information in assessing the doses

15 being provided, wherein it may recommend certain supplements that appear proper to the profile given. The individual is still responsible for selecting the doses but the system can provide feedback. When pills are purchased by the bottle, it is not possible to easily assess the combinations of pills being taken. A secure entry point at block 342 provides a hook to allow prescription entry access or access to dose schedules for other

20 authorized health care professionals. Access from the home pages continues via connector “A” at block 344 to FIG. 10 wherein a set of order processing pages are shown stemming from connection “A” at block 346. After registration a consumer may proceed by setting up a dose schedule at block 348. The dose scheduling page allows

establishing the number of times per day that doses are to be taken. The establishment of the schedule may be depend on, or are preferably automatically based upon, the dose interval requirements of one or more important prescribed medications.

Each dose selected for entry into the dosing schedule need not be the same as other doses during the same day, week or month, as the system allows wide customization (except in the case of prescribed medications, wherein the flexibility is intentionally constrained). The ease with which prepackaged doses can be handled and integrated into an individual's daily life encourage spreading out the doses to maximize effectiveness and minimize interactions. Scheduling elections are also made between a piggyback page at block 350 and a normal (monthly) scheduling page at block 352. Piggyback scheduling can be established at any time during the month, even if the month's supply of doses has just been received. The piggyback schedule is established as a temporary schedule of additions to the current month. The piggyback doses are preferably sent as a set of augmentation packets that preferably attach singularly to each remaining dose packet for the month. The elections of the piggyback doses are then either cleared or integrated into the regular monthly dose schedule at user option. Dose selection at block 354 allows an individual to select from supplements and over the counter medications spanning a wide array of health areas. An individual is provided with information about each supplement and may get in-depth information about supplements from a number of manufacturers. Lists of supplements and medications can be accessed by a search at block 356, by effect or indication 358, or by category 360. It will be appreciated that consumers select drugs for their desired effects and not for the chemistry involved, therefore, it is preferable within the present

invention to allow the consumer to select MS based on what they are trying to achieve. Categorizing by indication/desired effect has additional benefits, in that the system can properly suggest alternatives, such as suggesting Sam-E instead of Glucosamine, if one of the consumer's choices are contraindicated based on medical information or previously selected MS. For example, mood enhancement, inflammation pain relief, increase circulation, are all effect such as may be chosen from a indication/desired effect menu. The difference between indication and drug category can be easily appreciated in another example, antioxidants are a drug category that many MS fall into, including Vitamin C, Vitamin E, Pignolia extract, Grape Seed extract, etc., however, antioxidants are taken for a variety of reasons such as general health, arthritis relief, eliminating bodily toxins, purging, and so forth. It will be appreciated that the consumer may as a matter of convenience alternate between these various MS selection methods.

After proper dose selection, the user arrives at a selection list at block 362 relevant to their selected criterion. The selection list itself comprises item name, description, strength, and cost, while the user can click to get additional information about any of the items and may even open a link to the manufacturer for additional information. Preferably the selection list comprises a personal MS list providing rapid access for applying relevant doses to a dose schedule. The selection list shown at block 362 preferably provides a dose selection grid so that the user can apply the dose to the dose schedule which they have established. As described previously, a selected MS can be configured with a variety of tags, and the user may also add comments to go with the dose item selected. Examples: "Jane recommended this herb", "article in June

Vitamin News", and so forth. Tag categories of tags may be additionally selected to allow for rapid sorting. Automatic interaction checks are performed upon each selection, if a problem or cautionary note is in order then an interaction area as per block 364, opens up. The user can ignore, or delete the selected item. The interaction notes are still available at other portions of the system and important notes are preferably printed out with the package insert that is shipped with the package of doses, and even preferably on the individual dose packet if the precaution is of sufficient severity. When an individual has entered all the supplements and medications as desired, then they would access the order processing page at block 366 wherein all the final details of the order are handled. The individual will receive a set of individually wrapped doses labeled with their name, date and time that the dose is to be taken and a summary of precautions.

FIG. 11 and FIG. 12 further exemplify the functions and interface of the temporal dosing system of the present invention. FIG. 11 illustrated a web page according to an aspect of the present invention for allowing the user to select doses to be included within their order of individualized doses. The user name is prominently displayed, so as no confusion as to intended party can exist. MS selection can be modified in a number of ways, for example the drop down field allows the selection of the type of database upon which the MS are to be looked up. For example, the supplement database is illustrated, other databases can include over-the-counter, or prescription, medications and a wide variety of additional sources. The list is organized by category, wherein the MS are displayed according to the ingredient, instead of by indication/desired effect or other classification metric. A subcategory is shown by drop

down 418, shown displaying antibiotics.

The selection list itself 420 preferably comprises a number of information fields. A legend 422 indicates which fields are represented, which is exemplified showing a price per milligram 424, price per thirty tablets 426, and preferably includes miniature photos of the actual MS 428. The selection list 420 contains MS which may be found within the associated MS repository of the system, or be associated thereto for ordering purposes. The list of MS may be scrolled to reach any selection within the repository. The selection list includes names for categories 432 along with specific MS names 434 and basic information about the MS. Additional information may be looked up by clicking one or more of the hyperlinks 436 within the list to retrieve the type of information desired. Placing the cursor over any pill image causes a small pop-up to appear which indicates the type and dosage level of the pill. A note section 438 is provided to allow the user to take, or cut and paste, notes concerning the various medications and supplements. A pill cup representing a personal MS library 440, allows the user to click and drop any of the pill shapes 428 into the cup in order that the item be added to their personal MS library for use within a dosing schedule. It will be appreciated that a number of pill cups, or other such logical reservoirs representative of MS libraries may be provided.

FIG. 12 represents populating a dosing schedule 450. The user name "John Q. Doe" 452 is again represented for clarity. The name of the saved personal MS library is "DAILY" 454, and "ALL" weeks have been selected to be identical within the dosing interval which defaulted to one month. Alternatively, single weeks; such as week 1, week 2, week 3, week 4, and week 5 may be selected such that variations between

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weeks may be incorporated. The week field 456 may be toggled to allow for adapting an ALL-week schedule with changes to suit the schedule. A template name, "John at Home" was entered for saving the template built with the present page. The category "Antioxidants" is being displayed 460 from the personal MS library and is associated with the list 462, below it comprising a photo of the MS (pill in this case) 464, a description 466 and a scrolling bar 468. The user can scroll through the personal library, or originating template and click and drag pills from the list to the proper position of the dosing schedule 470. Each cell of the dosing schedule represents a single custom individualized dose which comprises a plurality of MS units, whether solid pills or other forms. The system may shrink the image of the MS (pills) 464 when they are inserted within the schedule so that adequate space remains for additional pills. In the example shown the user has selected three dosing intervals for their dosing schedule, and three rows were thus generated on the web page 472a, 472b, 472c. User selected times defined within the dosing preferences are shown as 8:00 A.M., 2:00 P.M., and 10:00 P.M. associated with each row of doses intervals. A selected MS from the personal library 462, may be dragged and dropped into any slot of the dosing schedule, and multiple clicks will drop multiple MS units. In addition, if the user wants to place the selected MS unit within each day of the dosing schedule they may drop it into one of the funnels 474a, 474b, 474c on the right side of the dosing schedule, whereupon an MS unit will be placed in each corresponding position of the schedule. MS units may also be removed by dragging them from the schedule into the removal bin 476. This simplifies both correction, and population of a row. It will be appreciated that the system does not allow the patient to select the number of pills or to set an arbitrary scheduling

for the taking of medications. The prescription is received in a secure transaction, and the individual is not allowed to change the overall number of pills being dispensed in accord with the prescription and they are not allowed to negatively impact the times at which the pills are to be taken. For example, if the prescription were to indicate taking the pills every 8 hours, then the patient would not be allowed, for instance, to schedule the taking of the medications at four or six hour intervals. This feature provides a large measure of health safety, since the individuals are substantially constrained to taking the correct prescription in order to gain the convenience of the individualized doses. As the MS units are selected, or alternatively entered into the dosing schedule, the relationship between the selected MS units is checked to look for interactions, while the MS units are individually checked against the health information provided by the individual to look for contraindications. Any information regarding possible problems, such as contraindications, negative side effects, and so forth are displayed within the window 478, which is provided with a scroll bar 480, and a print button 482. After all the desired doses are scheduled, the user can elect to have the list verified for content, or reimbursement purposes. For example, the user may elect to submit the schedule to their primary-care physician, in this case Dr. Smith, (as determined by optional setup information provided by the customer) by clicking the button 486. Dr. Smith is then sent an email, or other communication, containing the proposed schedule and information about the selected MS units. The doctor reviews the schedule, either in a form outside of the present system (such as a printout), or may view the dosing scheduling within the temporal dosing system in behalf of the patient. The physician then respond back to the user, or depending on preferences, submit the order for processing. Similarly, the

user's insurance company, Health Nut, in this case may be queried regarding what they are willing to reimburse by clicking the associated button 490. Additional forms of verification and notification may be provided, and the user may elect to have the order processed without intervention, whereby the order is just submitted by clicking on the submit button 492. The simplicity with which a user may establish individualized custom dosing is readily apparent within the preceding screen shots, and it should be appreciated that a huge amount of functionality is hidden within the upper row of selection mechanisms 494, for example, the Table of the dosing schedule may be manipulated with the conventional row and column selections and manipulations mechanisms.

The present system and method for providing individualized temporal dosing has described embodiments for interfacing with a prospective dose consumer, or practitioner, and the establishment of a dosing schedule for which individualized doses are prepared. In addition, the present system provides a system and method that provides economical and fault tolerant packetizing of the individualized doses.

FIG. 13 exemplifies an embodiment of an individualized custom packetizer system 510 according with an aspect of the present invention. The system has advantages over conventional packaging technology which involves the creation of identical product batches at stations arranged over a conveyor. The conveyor/station model requires a fixed periodic product flow while the stations do not lend themselves to a highly customized product. The present invention provides a system in which a fully customized product is assembled within a dedicated fulfillment center that is capable of efficient operation over a wide product throughput range. The embodied invention as

represented in FIG. 13 is shown with four pill towers 512, 514, 516, 518 each containing a repository of pills in pill bins that are arranged as two sets of parallel pill shelves 520, 522. Additional pill towers may be added to the system to increase pill selection. These pill shelves contain vertically-stacked rows of bins which are interconnected by a generally fixed set of traversal paths 524, 526, 528. A set of paths 530, 532a through 532d connect a packetizing station 534 to the pill towers 512, 514, 516, 518. The packetizing station 534 is provided with packaging materials from a receive station 536. Incoming compartmentalized dose assembly vehicles (*comdavs*) with their individualized custom pill doses are unloaded, such as by inverted rotation and optional vibratory jogging, to displace their contents into the packetizing station 534 which seals the individual doses as individual packets of pills. The completed packages are inspected within check station 538 prior to being boxed and shipped out.

FIG. 14 depicts a representative pill bin 550 containing pills 552 which may be dispensed to the *comdavs*. A bin housing 554a is preferably a clear plastic housing for retaining the pills with a lid 554b. The bin housing 554a is affixed to a dispenser housing 556 which contains a selector/dispensing mechanism 558 and a dispensing tube 560 with integral optical detector. A bin controller 562 contains a microcontroller that receives input from the dispensing mechanism 558, dispensing tube 560, while controlling optional bin jogger 564 and the front and rear error LEDs, 566a, 566b, and communicating with the shelf level controller (not shown). An electrical connector 568 supplies power and signals to pill bin 550. A front view of pill bin 550 is shown in FIG. 15. The pill bins 550 are preferably inserted within bin racks such that their dispensing tube is aligned with a *comdav* as it traverses the interconnection paths.

A primary element of pill bin 550 is the selector/dispensing mechanism 558 which controls the collection of individual pills from the bin and the ejection of each pill out of the dispensing tube 560. Selecting a pill from the bin requires that an individual pill be oriented and segregated from the remaining contents of the bin. It is preferable that the rate of dispensing for the pill bins match the speed of a moving *comdav*, such requires generally that a pill can be dispensed at intervals of 50 - 100mS. Initially *comdavs* are set within this embodiment to travel at a single speed which is equal to the maximum allowed loading speed of between one to four feet per second. The constant speed simplifies the processing of the *comdavs* while having little effect on throughput, as *comdavs* in fast transit would otherwise need to either wait for slower *comdavs* being filled, or would need a path to go around them. The addition of passing lanes for faster traffic may be added at a later time to provide additional temporal dose processing speed.

Achieving a given dispensing rate is simplified within the selector/dispenser of the present invention by pre-loading a series of separate pills into a cartridge, or compartments within selector 558. The preloaded doses thereby can be dispensed in rapid fire by selector 558 into a moving *comdav*. Substantial time can exist between successive *comdavs* into which a selected pill is to be dispensed, therefore the pill bin has ample time to pre-load a set of doses. The central operating computer dispatches the *comdavs* in a sequence so that time exists for pre-loading of a bin which has just dispensed pills. Duplicate pill bins should be in service for pills that have a high probability of being used as multiples per dose, so that multiple trips through the packetizing system are not required. The pre-load mechanism provides additional

light is also set up as a watchdog timer and it will turn on automatically if no messages have been received from the shelf controller or the bin controller in the preceding three minutes. This assures that a communication fault or processor breakdown will be detected quickly.

5 The loading of pill bins occurs "off-line", wherein the bins are preferably removed from the shelves to be loaded with additional pills. The central controller maintains a running tally of the number of pills loaded into each bin and each pill dispensed; therefore the central controller tracks the level of pills within every pill bin in the system. Work orders are dispatched for line-workers as the number of pills in a bin gets low, and
10 a backup bin is put into service in one of the pill towers (not necessary the same tower or location as the one that is getting empty). Once the new pill bin is on-line, the next pill assembly operation requiring that particular pill will receive pills dispensed from the new bin to assure proper operation, and then subsequently pills will be dispensed from the old bin until it is empty, at which time the new bin will be used. Empty bins are
15 removed and replaced with the same or other pills. Empty bins are cleaned and tested before being reloaded. A bin is loaded with new pills and cards containing information about the type, dosage, manufacturer, lot number, and a set of corresponding bar codes, are slid into a jacket on both the back and front of the bin. Each bin rack position also has an indicia with a unique alphanumeric name and corresponding bar code. The
20 controller can direct the service person as to the best location for placing any given pill bin to enhance the dose flow. The service person inserts the bin into a rack and tests the bin, then by using a bar code reader, (preferably a belt hung RF transmitting bar code reader) the bar codes on both the shelf and the pill bin are read. By reading this

pair of bar codes, the central controller will have stored the correspondence between pill type and the slot of the rack, and further will know that the pill is now on-line for being dispensed. A bin to be filled may also be filled with a fixed number of dummies (fake pills), wherein the first action of the controller is to dispatch a bin test vehicle, a small
5 *bindav*, to collect the dummies as a check on the functioning of the newly loaded bin. Unloading of the dummies by a test operation of the packetizing station checks that the proper number and order of pills was dispensed which verifies the operation of the new bin.

FIG. 16 is an embodiment which exemplifies computational resources 570 of the fulfillment portion of the temporal dosing system which is shown in a hierarchical block diagram. Orders for dose packets are received from any number of servers on the network, here represented as a web server 572. The orders are processed within a central order computer 573 which provides shipping, billing, pill requirements, and status information to an ERP (Enterprise Resource Planning) 574 system for the
15 enterprise. The central controller oversees the inventory of the pill bins whose status is maintained in a database 575, and the fulfillment of orders within the system. The central computer actually operates a number of program shells with the uppermost application being a device independent database driven application while the lowest level contains the communication protocols and may be configuration for the specific
20 hardware within the packetizing facility. One of the lower level software routines within the central computer contains a representation of the plant layout, procedures, timing, and current status. Schedules are calculated for the orders which are queued up within the database. The schedules are calculated based upon a set of rules which take into

account information about the order and the state of the packetizing plant. A track control computer 576 controls the operation of the linear electromagnetics (or alternative propulsion mechanism), position sensors, and switches along the fixed path upon which the *comdavs* operate. The embodiment described contains four pill towers and each is provided with its own controller 578, 580, 582, 584. The pill tower controller is preferably a PC computer such that the monitor provides tower status information. The pill tower controllers also communicate with the track controller 576 as it is the master authority on the position of the *comdavs*. The pill tower controller communicates with each shelf of pill bins within the tower, in this embodiment the tower has two racks, each containing five shelves. A dedicated controller 586a, 586b, 588a, 588b, 590a, 590b, 592a, 592b, 594a, 594b; on each shelf communicates with the tower controller and controls a set of bins 596a, 596b. The shelf controller is preferably implemented with an small embedded PC controller. Each pill bin also preferably contains a small microcontroller to monitor and control the dispensing process within the bin and provide for the communication of status information with the shelf controller. The bin controller, for example, may be implemented as an inexpensive microcontroller such as a PIC16C64 from Microchip™ Incorporated. The bin controller is given dispensement directions by the shelf controller based on information received from the tower controller driven by the central controller. The bin controller is very important as it can read bar codes from passing *comdavs* and will correctly dispense a set of pills into the correct compartments of a particular *comdav*. The power of the bins for reading passing *comdavs* is also useful for updating location data on each *comdav*. The bin controller generates communication in response to communications from the shelf controller (an

preferably not independently which is asynchronously to other bins), but can trigger a common fault line, or event line, to asynchronously get the attention of the shelf controller. It is possible to operate the entire individualized custom packetizing system from a single computer, however doing so would hamper performance of the system, perhaps even miring it with I/O, while complicating the scaling of the system to different size order fulfillment systems. Imagine the difficulties with central computer controlling and receiving status reports from 50,000 individual pill bin controllers. It is possible to reduce the amount of interaction with the bins, however, a lowered level of communication reduces the speed at which problems will be detected within the system. The preferred hierarchical structure removes this I/O bottleneck while additionally providing increasing levels of hardware independence, and safety.

FIG. 17 depicts the flow of the manufacturing process 600 for creating the individualized custom doses according to the dosing schedule established by the user or practitioner. The process is triggered at block 602 based on time in relation to the desired delivery date and the status of the system. The order of individualized doses is received within the packetizing system at block 604. A vehicle containing a sufficient number of separate collection areas is directed at block 606 to the pill bins. The pill bins are directed to eject pills at block 608 into the separate collection areas within a particular *comdav* vehicles. The *comdav* vehicle traverses the circuitous routing of the pill bins until the desired set of individual doses have been collected in the separate collecting areas within the *comdav* vehicles, at which time the collecting areas are separately unloaded at block 610 into separate, or segmented packaging wherein each scheduled dose is distinctly retained so that the pills, or other MS, comprising the dose

may be separately utilized as a single individualized dose. Markings are preferably applied at block 612 to the individual dose packets to aid identification, and the process is completed at block 614 until another dose order arrives.

FIG. 18 is an embodiment of a *comdav* (compartmentalized dose assembly vehicle) 700, with a view of the top shown. This *comdav* is implemented with a round cross-section and travels in a preferably transparent tube as it traverses the racks of pill bins. The front of the *comdav* 702 preferably contains a bar code 704 which can be read by the pill bins as the *comdav* 700 passes on its traversal of the system. It should be appreciated, however, that bar codes are a design choice and alternative registration mechanisms may be deployed without departing from the present invention. A collection of dose carriers 706, 708, 710, 712 are attached to one another and the front of the *comdav* 702. A row of top-side wheels 714, 716 on these *comdav* carriers lower the friction and stabilize the *comdav* within the tube. The interior of each carrier 706, 708, 710, 712 within each *comdav* has dividers 718a through 718L such that compartments 719a through 719L are formed within the carrier. Individualized pill doses are loaded into these compartments one by one through a slotted aperture 720, 722, 724, 726. In the side view of FIG. 18 the main front and rear wheels 728, 730 of each *comdav* carrier can be seen. A linear form of propulsion is depicted wherein the side of the *comdav* contains embedded magnets 732a through 732d1, such as powerful "rare-earth" magnets. The magnets within this embodiment of the *comdav* form one half of a linear electromagnetic drive mechanism, which will be discussed in greater detail later. A cross section view of the *comdav* is shown in FIG. 20. The slot 720 can be seen as the entrance to a curved path into the pill compartment, having an overlapping

cover 721. Use of this curved path provides a cover to prevent pills from being bounced out of the pill compartment 719a through 719k while it smoothly transitions the pill into the compartment.

The *comdav* preferably rides in a tube 750 in FIG. 21 shown with electromagnetic strips 752a, 752b. One strip 752a in FIG. 22 is shown comprising a series of simple coils along its length. This linear electromagnetic drive mechanism for the *comdavs* is located along the sides of the tubes which contain electromagnetic strips which are composed of a series of inductive windings arranged in a series of phases, and controlled within sections. The alternate activation of the phases of inductive windings creates an electromotive force between the inductive windings and the magnets 725 embedded on the sides of the *comdav*. Conceptually, the windings operate similar to the windings in a conventional rotating motor, however the windings in this case are spread out linearly to effect a linear translation instead of a rotation. The electromotive forces constitute a driving force which is controlled directly by the track controller. Using this form of linear electromagnetic drive has a number of advantages. The speed of the *comdav* can be precisely controlled by the track controller. Each *comdav* need not contain its own power source and drive mechanisms, wherein the resultant *comdav* is a simple sanitary mechanical structure requiring no drive electronics and controls. Each *comdav* may is preferably subject to regular steam cleaning and sterilization. Although alternative propulsion means may be utilized, such as motor drive wheels, it should be appreciated that the interaction of driving wheels on a self-powered *comdav* with the tubes would be expected to create a certain amount of debris which would need to be prevented from contaminating the compartments of the *comdav*. Additionally, the use of

linear electromagnetic drives allows the *comdav* to be conveniently rotated within the tube for banking at the corners at high speed and for controlled inversion within the packetizer for unloading the pills from the compartments. A further advantage lies in the ability to garner a huge speed advantage. Proper positioning of the magnets and inductive windings can result in reducing the forces on the wheels to near zero. With low friction, banks (non-spill) corners and a powerful drive mechanism the *comdavs* could be propelled at high speed to more readily assemble the requested doses.

The transparent plastic tubes 750 can also be seen in FIG. 13 looping around the pill towers in large ovals and connected with the packetizing station. The tubes are shown routed helically in an ascent or descent around each pill tower, and is the reason the pill towers are shown paired off, with complementary towers oriented with an up and a down direction tower. A *comdav* can be routed off the main tube to a pair of pill towers and will pass horizontally among each shelf of the two towers before arriving back again on the main tube. Although only four towers are represented in FIG. 13, any number can be added to the system. When a set of doses according to an order (or a portion of an order) have been loaded into the compartments of a *comdavs*, the *comdav* is routed to the packetizing station for being unloaded, and packetized.

FIG. 23 illustrates a representative packet-string 760 with a series of separate individual packets 762a through 762f which may be separated from the packet-string.

The packets may be fabricated from inexpensive materials, such as cellophane, although material choices abound. Each packet 762a through 762d contains a set of pills 763 according to the custom dose selected by the user. Packet 760 are shown providing a small dose retention area and it will be appreciated that the packet, or other

form of container being utilized to packetize each dose may configured of a size appropriate to the number of pills being retained. A packet, such as 762a, can be separated from the string by the perforations 764. For clarity, labels are not shown on the packets, although preferably each packet will be labeled with the persons name, day, and the date which the dose is to be taken along with an optional time specifier depending on user selections placed with the order (i.e. morning, noon, afternoon, evening, night, 8:00 AM, 10:00AM, etc).

FIG. 24 is a representation of a "piggyback packet-string" 765. The piggyback string 765 is shown with a attachment area 766 that for instance may have an adhesive strip and a set of small pouches 767a through 767d which contain pills 768a through 768d. Piggyback packet-strings can be used to add pills to an existing set of pill doses. For example, a user receives their monthly shipment of dose packets and then a week later is issued a new prescription, or desires a new supplement. Rather than ordering and having to carry a separate bottle, which may be very inconvenient, as well as easy to forget, they can order a piggyback set of doses. The piggyback string in this embodiment is attached "piggyback" to the original string of packets to increase user convenience.

FIG. 25 is an elevation view of a pill tower 770. The top of the pill tower 772 is shown built up to a floor 774 on which equipment may be positioned and from which a service person 776 is shown descending into the center of pill tower 772 on ladder 778. This floor provides a deck over which bulk pill storage and bin filling can be readily accomplished. The floor 774 has openings corresponding with the spaces between the two racks within each pill tower to allow each pill tower to be serviced easily from the

upper level.

FIG. 26 depicts a cross section of the pill tower and the access space from the upper level. On the upper level, bins can be filled and carted to the correct pill tower and lowered down into the center of the tower where they can replace depleted pill bins.

5 A collection of pill bins 780 are depicted loaded upon pill shelves 782. A helical *comdav* tube 784 is shown passing horizontally across the face of each shelf while sloping upwardly 786 on one end of the pill tower 770 to climb up to the next level of the tower. The *comdav* tube 784 then passes from the highest shelf to a downward spiraling tower by a horizontal curving section 788. A *comdav* is shown 790 in the process of
10 traversing a shelf within tower 770. *Comdavs* are preferably dispatched on an as needed basis and sections of magnetic propulsion for the *comdav* tubes 784 are only energized as needed to propel a given *comdav*. This "as needed" deployment when coupled with intelligent scheduling by the central controller provides a system which is fully traffic scalable while retaining energy and overhead efficiency.

15 The central computer within this embodiment of the present invention makes the scheduling decisions based on the status of the physical custom packetizing system and the queue of custom dose orders to be fulfilled. The central computer sends an order to the track control system which dispatches a *comdav* and controls the movement of the *comdav* amongst the pill towers, routing it as necessary to fulfill the
20 custom dose order. The pill towers are similarly directed so that the pill bins will dispense pills into the *comdav* according to the consumer order. The *comdav* therefore proceeds around the pill towers, as the bins record the passing of the *comdav* and even read off its unique bar code; the exact position of the *comdav* is therefore known at all

times. Bins which are to dispense a pill into the *comdav* are provided with an alert signal when the *comdav* has almost reached the bin. The pill bin upon reading the correct bar code from the front of the *comdav*, synchronously dispenses pills as it also senses the openings for each pill compartment along the length of the *comdav*. Pills are "launched" (ejected) via the dispensing tube into each *comdav* compartment which is to receive a pill to comprise a dose. The shape of the *comdav* compartment prevents pills from bouncing out of the compartment. The *comdav* typically is of a length to accommodate the loading of a months supply of doses within the custom order. Each day's supply may consist of a number of doses of different supplements and medications. For example, in a single day a person may take four doses of supplements and/or medications with no two of these doses being the same. Dispensement into a *comdav* therefore is performed with a pill being dispensed into each compartment or each modulo (2,3,4...) of a compartment according to the dose order. If a large number of doses during the day are required, then additional cars may be linked to the *comdav* prior to it being sent out to the pill bins, a *comdav* having more compartment may be sent, or the order may be split across multiple *comdavs*. Pills are added to each dose residing in each compartment of the *comdav* as the *comdav* proceeds among the pill bins.

When the dose order has been fulfilled, the *comdav* is routed to the packetizing station where the pills are unloaded from each compartment of the *comdav*. The doses may be loaded onto an intermediary set of collection compartments or unloaded directly into individual packages or compartments of a larger package. The set of doses can be checked prior to packaging to assure that each dose is correct according to the order.

This can be performed with a camera which scans each dose comparing number size and colors of each pill against metric in the data-base. In addition the MS contained within the bins may be configured with machine readable markings, such as adding text/graphic indicias, color coding, adding small bar-codes or 2-D optically scanned arrays, and so forth. It will be appreciated that microparticles may be included within the MS which aid in its identification, for example in a similar manner that microfluorescent filaments are added to the powder of explosives to encode a batch number for the purposes of tracking. Another alternative is found in a recently introduced form of RFID has been developed which has a diameter less than that of a human hair and yet is capable of retaining a unique ID which may be externally registered. It is preferable that multiple methods are utilized for registering that the proper MS have been selected within a particular dose packet. Doses that appear to have been "mis-filled" may then be checked by a human operator and corrected if necessary prior to being packaged. The series of doses can then be packaged for shipment.

FIG. 27 illustrates an alternative form of *comdav* path 790 upon which the *comdavs* may be moved between the pill bins. A tube 792 with interior 794 with a support 796 supports one or more alignment protrusions 798a, 798b. The alignment section shown are ridges although alternatively grooves could be used. These alignment sections guide the *comdav* and may support it as well.

FIG. 28 depicts a cross section for an alternative *comdav* 800 which corresponds to the path 790 shown in FIG. 27. The vehicle has an exterior shell 802, and grooves 804a, 804b for receiving the ridges 798a, 798b of FIG. 27. Wheels 806a, 806b protrude

through the underside of the vehicle 800 to provide locomotion as driver wheels driven by geared motor 808 through drive axles 810a, 810b. Use of ridges 798a, 798b and corresponding grooves 804a, 804b within the *comdav* may largely restrain the vehicle 800 from experiencing side to side movement while traversing the length of the tube.

- 5 The *comdav* in this embodiment could contain any of various forms of motors for driving one or more wheels. Furthermore, such an embodiment may have an internal source of power located on the *comdav* itself or received while the *comdav* travels along the path. Another embodiment can be created wherein the alignment sections are attached to a non-tubular support for moving between the pill bins. The cleanliness of the tubular
10 embodiments are clearly preferred over open embodiments while the electromagnetic drive is preferred for the speed and safety which may be attained.

It should be noted that although the above embodied design contains a variety of checks and tests, the system even without such checks should experience few errors. However, since medical doses are being dispensed it is only prudent to include a variety
15 of checks to further reduce any possibility of error.

It will be appreciated that the invention can be implemented in a variety of ways without departing from the inventive concepts described herein. Pill bins provide a controlled manner of dispensing pills. The shape, method of dispensement, and operation of the pill bins may vary without departing from the teachings herein. A
20 multilevel computer arrangement was described for controlling the assembly of doses within the packetizing system, however, the process control functions involved may be accomplished by any of a wide range of system architectures and individual computers. Bar codes are used for identifying each *comdav* as well as for locating pill bins and

shelves, while alternative locating means can be used. Position detection can be used wherein each *comdav* is kept track of by the controller, while electronic RFID tags, OCR and numerous other locating/identifying mechanisms exist which may be substituted.

The arrangement of the pill bins into towers, as exemplified, is by no means the only

5 manner of arranging the bins of pills. Various shapes and arrangement can be substituted which will similarly allow a vehicle to collect pills from any of a number of pill dispensers. A linear electromagnetic drive is described for moving the *comdavs* within tubular paths between the various pill bins. It must be understood that vehicles containing conventional motor driven wheels may also traverse these tubes.

10 Furthermore, it is to be understood that the tubes may be replaced by other pathways between the pill bins. With a single layer of pill bins the *comdavs* can be configured to determine their own path from one bin to the next. While on a multi-layer arrangement wide paths can be created allowing *comdavs* to pass one another in transit to a pill bin. Various forms of packaging may be used for holding each set of pills that constitute an

15 individual dose. These forms may comprise sealed cups, envelopes, boxes, trays, and the like. The *comdav* may likewise be loaded with the unsealed packages into which pills making up a dose are dispensed, whereafter the packetizer need only seal the package to form an individual dose. Additionally, the doses being collected may be in the form of liquids. Many liquids exist such as lotions, oils, and creams, along with

20 liquid vitamins and minerals. These liquids may be dispensed into small packages for single uses, or a number of liquid supplements can be added to a vessel which is subsequently sealed to create a dose. Unfortunately, as a substantial percentage of supplemental and medicinal liquids may chemically interact with one another, the

exclusive use of liquid packaging for all dose forms is far less preferable.

It will be appreciated that the invention can be implemented in a variety of ways with the embodied web site and specific interface characteristics being provided as examples and not limitations of the described invention. Accordingly, it will be seen that this temporal dosing system and method provides a practical and convenient means for resolving many problems, issues, and risks associated with the current pill dispensing techniques whereby individuals must open containers, extract pills, collect doses, and maintain their pill stocks.

Although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Thus the scope of this invention should be determined by the appended claims and their legal equivalents. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method

step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for."